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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CONLEY, SEAN EVERETT	
ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,777	CARLSSON ET AL.	
	Examiner	Art Unit	
	SEAN E. CONLEY	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *12-16 and 26-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 17-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/10/2005, 9/2/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I, claims 1-11 and 17-25 in the reply filed on October 22, 2008 is acknowledged. The traversal is on the ground(s) that the Office has not shown that the claims of Groups I and II do not relate to a single inventive concept under PCT rule 13.1. Specifically, the Applicant argues that the cited references neither anticipate nor render obvious the claimed invention. The Examiner respectfully disagrees for the following reasons:

Regarding anticipation

The claims are not anticipated by either of the cited references. Therefore, the Applicant's arguments are moot.

Regarding obviousness

The Applicant first argues the following: *"Applicants remind the Office that "[t]he key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious." M.P.E.P. §2142 (emphasis added)."*

This argument is not persuasive since there is no rejection under 35 U.S.C. 103(a). The restriction requirement was made in accordance with PCT Rule 13.1.

Further the Applicant argues that *"one of ordinary skill in the art would have had no expectation that the replacement of glucose in a solution according to Jonsson with the amino sugar NAG disclosed in Breborowicz would have resulted in a viable medical*

solution because both references are silent regarding the toxicity associated with the terminal sterilization of amino sugars."

The Examiner respectfully disagrees. Breborowicz discloses the advantages of substituting N- acetylglucosamine (NAG) for glucose in a peritoneal dialysis fluid to produce a more biocompatible fluid. Therefore, it would have been obvious to one of ordinary skill in the art to substitute the glucose of Jonsson et al. with NAG to achieve the advantages exemplified by Breborowicz. The advantages disclosed by Breborowicz are sufficient to reasonably expect that the substitution in the invention of Jonsson et al. would result in a viable medical solution.

In addition, Rovati et al. (U.S. Patent No. 3,697,652) teaches that it is well known to heat sterilize solutions comprising N-acetylglucosamine (see columns 3-4, examples 2-6).

The restriction requirement is still deemed proper and is therefore made FINAL. Claims 12-16 and 26-30 are withdrawn from consideration for being directed to a non-elected invention.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-11 and 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jonsson et al. (U.S. Patent No. 5,536,469) in view of Breborowicz et al. (document titled "Replacement of Glucose with N-Acetylglucosamine in Peritoneal Dialysis Fluid").

Jonsson et al. discloses a sterile medical solution containing glucose or glucose-like compounds for peritoneal dialysis (see col. 1, lines 54-56). The content of the glucose-like compounds are preferably in the order of 40% by weight (see col. 1, lines

60-65). Jonsson et al. further discloses heat sterilization of the final solution (see col. 2, line 2) between a temperature of 110°C and 150°C (see col. 2, line 10), specifically 121°C (see col. 5, lines 1-5). Heat sterilization necessarily involves some degree of heat transfer provided by convection, conduction, and thermal radiation in the form of non-ionizing infra-red radiation, and therefore interpreted broadly heat sterilization meets the definition of radiation sterilization. Jonsson et al. also discloses the final solution optimized at a pH between 6.5 and 7.5, preferably about 7.0 (see col. 2, lines 55-56) and the solution mixed and diluted to 1.5% glucose content after sterilization (see col. 2, lines 57-61). Jonsson et al. further discloses the solution contains low levels of cytotoxic degradation products (see col. 4, lines 3-5). Jonsson et al. discloses the solution in a bag system (see col. 4, lines 11-20) which is a container comprising at least one compartment.

However, Jonsson et al. does not specifically disclose a medical solution containing one or more acetylated or deacetylated amino sugars nor does Jonsson et al. specifically disclose the preparation of a final medical solution wherein the pH is 7.4.

Breborowicz et al. teaches partial replacement of glucose with N-acetylglucosamine (NAG) in peritoneal dialysis fluid results in advantageous preservation of the peritoneal membrane (see page 365, left column, paragraph 1). Breborowicz et al. also teaches supplementation of the dialysis fluid with hyaluronan, a human glucoseaminoglycan, results in the advantageous suppression of inflammatory reaction induced by peritoneal dialysis (see page 365, right column, paragraph 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Jonsson et al. in view of Breborowicz et al.

One of ordinary skill in the art would be motivated to combine Jonsson et al. in view of Breborowicz et al. because Breborowicz teaches it is advantageous to partially replace glucose with N- acetylglucosamine (NAG) which is more biocompatible, giving a solution comprising both NAG molecules and the physiologically compatible constituents glucose molecules.

One of ordinary skill in the art would be motivated to practice the invention of Jonsson et al. in view of Breborowicz et al. wherein the one or more acetylated or deacetylated amino sugars is human glucoseaminoglycan because Breborowicz et al. teaches supplementation of the dialysis fluid with hyaluronan (a human glucoseaminoglycan) results in the advantageous suppression of inflammatory reaction induced by peritoneal dialysis.

One of ordinary skill in the art would be motivated to optimize the final medical solution wherein the pH is 7.4 because Jonsson et al. teaches the final peritoneal dialysis solution optimized at a pH between 6.5 and 7.5, and it is well known in the biological field that pH 7.4 is the common blood plasma pH and therefore an optimally biocompatible pH.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-11 and 17-25 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-4, 7-12, 18-19, and 21-24 of copending Application No.

10/538,791. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: claims 1-4, 7-12, 18-19, and 21-24 of copending application 10/538,791 recite a method for preparing a medical solution.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Conley whose telephone number is 571-272-8414. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 12, 2009

/Sean E Conley/
Primary Examiner, Art Unit 1797